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ABSTRACT

The Stanford University Medical Center consists of three main units: a medical school, a set of outpatient clinics, and a hospital. Financing of the center's functions cannot be carried out without federal support, and a network of relationships with government agencies has emerged. The impact of these relationships was discussed with key administrators in a number of areas of the organization: personnel, finance, some aspects of research management, legal services, facilities construction and operations, and student assistance. The impact in personnel is broad, affecting costs in recordkeeping and extra personnel but also effecting social benefits. In finance the effect of regulation is so continuous (as contrasted with seasonal or annual) that computer programs have been developed to take account of almost daily changes in regulations. In facilities the relationship is based less on cost or extent than on the great number of agencies and rules involved. Regulations affecting admissions and student progress have brought changes in admission policies and procedures, the handling of student records, and the control of student loan monies from the government. In addition to funding, the federal-institution relationship in the area of research involves the control of the substance of research, as in research on human subjects, animal care, and genetic research. The relationship in legal services is characterized by the increase in attorneys on staff: in 1973 the medical center used the services of one attorney half-time; in September 1977 the staff consists of four full-time-equivalent attorneys. An estimate is given of the amount of time used by this staff in complying with various federal authorities, totaling 75 percent. (MSE)

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The Stanford University Medical Center and The Federal Government

A Report for the Sloan Commission on Higher Education and Government

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INTRODUCTION

The Stanford University Medical Center consists of three main elements, a medical school, a set of out-patient clinics, and a hospital. They are joined together administratively under a Vice-President for Medical Affairs, who is also Dean of the Medical School. The ties that bind the three units are more than simply administrative; more fundamentally, they are interlinked parts of a system that must accommodate the requirements of the training of medical doctors and biomedical scientists, basic and clinical research, and patient care.

The accompanying table provides budgetary and statistical information about the Medical Center and its component parts. The picture it shows is substantially similar to that of many major university medical centers, except that Stanford owns its own hospital, which is not true of most, and the Stanford profile may show a heavier emphasis on research than is typical.

What the picture shows graphically is the extent to which the Medical Center is involved with the Federal Government. That relationship long ago passed the point at which it could be described by saying that Federal financing is important to the conduct of medical training, research and patient care. It is now the case that the performance of those functions at Stanford and other similar institutions cannot be carried out without the Federal Government. The government now stands, in its various guises, as patron, customer, monitor, regulator, supplicant, seducer, director and full partner in the operations of the modern university medical center.

It is, in fact, misleading to speak of <u>a</u> relationship. What has come to exist is a network of relationships that is varied, complex, and far from being of a single piece. In a sense the university medical center is a university... plus. That is to say, as part of a university it is a party to many of the relationships that characterize the university-government interaction. The support of research and training in the medical school provides opportunities and obligations that are essentially similar in kind to those in other parts of the university.

Similarly, like the rest of the university, the medical center interacts with the government in a variety of ways that have little to do with the fact that teaching, research, and patient care are the institution's primary activities. The National Labor Relations Act, the Social Security Act, ERISA, the Fair Labor Standards Act, and a host of others affect medical centers and universities not in their capacities as specialized institutions, but rather as institutions doing business in an increasingly regulated economy.

In addition, and unlike any other part of the university, the medical center faces the government as a key provider of a critical consumer service -- medical care -- for which the government is assuming a growing responsibility. That aspect of the relationship has generated both opportunities and problems and is the most open-ended of all the many relationships which exist. The critical nature of the service and the high political interest in its content, form and cost produce tensions which are as yet far from being resolved.

This study attempts to illuminate some of the important ways in which government and medical center interact at Stanford. The qualifier "some" is worth special mention. First, this is not a comprehensive study of medical center-government relations. Rather, it is a look at some key elements of that relationship. For example, in assessing the administrative costs of doing business with the government we have made no effort to accumulate data on the costs that are found in the budgets of individual departments and laboratories. Those are a large and important part of the picture but a shortage of time and hands made that job too difficult to do.

Second, even in those areas which we looked into in some detail, our guiding rule was not "Be precise to the final dollar," but "Take pains not to be misleading."

Third, we have tried to get some sense of the qualitative effects of the relationships we studied. Questions like, "What difference does it make?"; What benefits do you derive?"; How would your work be different if the government were not in the picture?" are important, but very difficult to get at. Those

attitudes and their relationship to reality are central to the public policy questions which, in the final analysis, are the object of our inquiry. If we were to continue and expand our study, we would assign a high priority to deeper and more systematic study of such questions.

Fourth, in all of higher education medicine may be unique in the extent and complexity of the interactions among federal, state, local, and private regulatory programs. This is most evident in the area of facilities construction and operations, but it is also true in training and to a lesser degree research. We do not think that we have succeeded in sorting out the pieces of the puzzle. In general, our approach was to try to account for any activity in which we could detect a significant federal presence, even though the immediate manifestation of the activity might be state, local or private.

Fifth, and last, given the limitations of time and resources, we decided to concentrate our efforts on those areas of activity that either are unique to medicine or have an unusual or particularly significant impact on medicine. An obvious example of the former is Medi-Care; an example of the latter is the regulation of research involving human subjects. Those regulations apply throughout the university, but they have special meaning and force in clinical medical settings where the health of patients may be at risk. In contrast, we have not looked at those aspects of research management which are no different in practice or principle from the rest of the university.

In the end we decided that the best way to tackle so large a subject with so limited an armory is to concentrate on a manageable number of key areas -- those which, because of their substantive importance or strategic location, illuminate major and representative areas of the relationships in which we are interested. These are personnel services, finance, some aspects of research management, legal services, facilities construction and operations, and student assistance.

Our procedure in each of those areas was to identify the key people and to send them a copy of our questionnaire (attached). We asked them not to fill it out but to think about the questions in it, find out whether they are answerable, and think of any other questions relevant to their area that we had not included. We then interviewed each person, using the questionnaire as the basis for our discussion. At the end of each interview we left with an agenda

of tasks for our respondents and us to perform and a schedule for their completion.

What follows from this point are descriptive reports for each of the areas we studied. At the end we shall draw such conclusions as we think warranted, and we shall have some observations about the present and the future.

Personnel

While the impact of Federal regulations varies from Department to Department, there are few departments affected so widely and profoundly as Personnel. The impact has been from many pieces of legislation affecting all the major functions of personnel activity, and involving increased expenditure both for additional personnel and for equipment. Among the most important pieces of legislation have been the Equal Pay Act of 1963, the Social Security Act, the Employee Retirement Income Security Act 1974 (ERISA), The Fair Labor Standards Act and the Age Discrimination Act of 1967, and the Civil Rights Acts.

The costs across the Department are uniformly large. Benefits section, for example, calculates 750 man-hours added and $100,000 expended as a result of the implementation of ERISA alone. (See also: Legal Services). The same Act is particularly difficult to respond to. It further requires dual reporting to the IRS and to the Department of Labor.

In the Employment section, a similar impact is felt. It is estimated for example, that as much as 25% of staff activity relates directly to compliance with Federal regulations. Records, required to be kept by Federal mandate, would be considerably reduced, and some areas abandoned altogether, but for the legislative requirements.

Equal opportunity legislation has led the Education and Development section to hire two additional staff and a subsequent expenditure of some $45,000. The law further provides for career counseling and other related programs which did not exist previously.

The Fair Labor Standards Act has similarly led to an additional staff member in the Compensation section, with concomitant costs in equipment and salary. In Employee and Labor Relations, costs are even greater, with three additional staff employed, additional files kept, new offices provided and so on. The same pattern is repeated in administration services, with staff added and functions undertaken.

None of the measures which have produced this response are aimed at or tailored specifically for universities or hospitals. Rather, they are designed to provide

for and protect the welfare of employees generally. ERISA is a very clear example of this form of general social legislation, seeking as it does to protect the retirement rights of all employees. As we have seen in the Office of Student Affairs, the costs are largely institutional, involving additional administrators, more files, more reports, additional office space. On the other hand the benefits are personal, rather than institutional. That is, they affect staff in the employ of the Medical Center, rather than the institution itself.

These trends again raise the question of whether Stanford would have undertaken such measures in the absence of Federal requirements to do so. Clearly, we can never know for certain. For the most part, however, Federal action was a recognition of a real social problem, and so some institutional response would undoubtedly have been forthcoming, but later, less sweepingly, and at a slower rate.

In the words of a personnel executive, "the regulations appear to 'prescribe and proscribe' employer-employee contacts. The effect is to 'restrict the employer's options in maintaining the ,,, relationship and, as such, deny an individual employer the opportunity to creatively tailor programs to fully meet the needs of both the employer and the employees.'" As some Personnel people see it, the pendulum has swung so far in the direction of protecting employees' rights that the ability of the institution to function efficiently and find solutions suited to its circumstances has been compromised.

While this appears to be the major disadvantage, apart from the costs cited above, there are also benefits. To begin with, the measures that concern us do protect and enhance the rights of all employees, and promote more equitable employment practices both in the hiring and maintenance of staff. In the area of Education and Development, government intervention has meant, in the words of one respondent "Constant interaction between patient health care auditing and the educational process," and the requirement that "organized educational programs for staff (be) provided." Further legislation has led to "a comprehensive view of the educational process in health care centers (which) encompasses (both) staff development and patient education."

In the Benefits section, improvement has been seen in personnel and compensation management, a feeling shared by the Employment section. In short, it seems

that while Federal regulations relating to personnel have resulted in heavy costs to the institution, the benefits to employees, both in terms of concrete financial and in-kind benefits, and also in terms of increased sensitivity in the employing process, have also been considerable. The impact of the Federal Government is therefore neither wholly positive or negative. Rather, it is a mixed blessing. For administrators and the governing process in Personnel, it presents many difficulties. For those employed, the benefits are clear and considerable.

BUDGETS (1976-77)

Consolidated Budget		
Clinics	$ 12,000,000	
Hospital	70,000,000	
All other Departments (excluding Medical Center)	242,000,000	
TOTAL		$324,000,000
Medical School Budget		$ 45,000,000
Grants and Contracts from Federal Government (1975-76)		
(Direct Expenses Only)		
Research	$ 20,300,000	
Training	4,000,000	
Capitation	500,000	
TOTAL		$ 24,800,000
Patient Care		
42% of patients funded by Federal and State Programs		
Faculty - (Members of the Academic Council 1976-77)		
Medical School	303	
All other Faculty	829	
TOTAL	1132	
Student Body (Medical School) 1976-77		
M.D.	404	
Other (M.S., Ph.D.)	155	
Interns and Residents	395	
TOTAL	954	
Student Body (Other Than Medical School) 1976-77		
Undergraduates	6412	
Graduates and Professionals	4753	
TOTAL	11165	

Table 1

Finance

In its capacity as the planner and provider of financial service for all the major sections of the Medical Center, the Finance Department has some umbrella responsiblities which make its functioning unique. Since it relates so directly to each department, it is affected by a myriad of regulations and controls, both from the Federal Government and from the State. So important are these that the main planning document for the 1977-78 Hospital budget opens with a discussion of their likely impact.

As outlined in that paper, these regulations fall into two major categories. First, many regulations relate to licensure, that is, codes and requirements which must be met if the Hospital is to be licensed by the State and by the Federal Government. Such licensing is, of course, a condition of Federal reimbursement for a whole variety of service, such as Medicaid and Medi-Care and for loan funding for medical purposes. A second category of regulations governs reimbursement itself. The level at which the hospital receives reimbursement through Federal health programs for patient care is of vital concern to the Department, and constitutes a major area of impact on its workings.

Some major generalizations describe the response of the Finance Department to Federal regulations. To begin with, the process is continuous, not sporadic. While a department such as the Office of Student Affairs may be required to deal with several major sets of regulations during any one year, it is likely that these regulations will have an impact during specific periods of time. A very different pattern is typical of separate Finance Department interactions with Government, which are better seen as continual. Indeed, the process is sufficiently continuous to persuade the Department to adopt a procedure by which computer programming can take account of almost daily changes in Federal regulations.

A second generalization concerns the limitations within which the Department must work. Two constants are at work. First, hospital care must be maintained at an acceptable level, both for patient care and for clinical teaching. Second, the Center cannot operate at a loss, if it is to continue to be viable. Given

these two conditions, the major role of the Department is to find ways of complying with the many regulations which affect the financial operations of the Center, while achieving a profitable outcome, and ensuring high quality patient health care.

Third, while the whole area of Federal regulations of medical care is best characterized as "very active, but uncertain," one major trend is readily discernible. Federal control of medical care is increasing. A major target in this process is the control of finance. By controlling requirements which hospitals must meet, and by controlling the levels at which hospitals will be reimbursed, the Government is indirectly controlling the levels of reimbursement which doctors will receive. The job of the Finance Department is thus pivotal in this process. While resisting unwanted changes in Federal policy with one hand, finance administrators also have to deal with their own doctors and staff to cut costs and charges to meet reduced Federal reimbursement levels. Finance administrators thus act both as antagonists of the Government, in seeking adequate financing, and also as allies of the Government, in placing constraints on the medical practitioners by being the carriers of the news of limited finance for medical care.

The impact of Federal regulations is everywhere evident. For example, auditing has become an almost continuous process. So long as each Federal agency has its own auditing procedures, this is a condition which is likely to remain. In response, the staff time spent in auditing is similarly continuous, and costs in programming new ways of providing data for the auditing processes are also extensive.

Perhaps the most evident impact has resulted from the introduction of public programs of health insurance. Billing for these programs, for example, involves most of the 175 people involved in the whole billing process. Approximately 40 people deal exclusively with Medicaid and Medi-Care. When physicians began to be billed separately under 1974 regulations, 25 people were take on, a dramatic example of Federal impact.

Apart from costs directly related to staff, the difference between the public and private reimbursement levels of these health care costs is considerable. Public reimbursement procedures involve more paperwork, more time in actual bill

processing, and lower levels of reimbursement than the private sector. While increasing numbers of patients would have added to the paper work-load irrespective of Federal intervention, increasing numbers of Federally-funded patients exacerbate the natural increase in paper-work. It is also clear that the gap between public and private levels of health care reimbursement is increasing. At present, this gap is 18%. Since Federally-funded patients now constitute 40% of the total patient load, this gap represents a considerable and direct cost to the Center.

Several major regulations presently under consideration would affect this reimbursement problem. The Talmadge Bill (S.1475) would "establish limits on reimbursement for routine per diem operating costs based on a hospital classification system." The Carter proposal (H.R. 6575, S.1391) "establishes a cap on hospital revenue keyed to GNP deflator and past aggregate hospital cost increases." This would allow a 9% increase for the next year. It is explicitly conceived of as a short-term solution to the problem of rapidly rising hospital costs, and it would presumably be followed by a more systematic and detailed regulating scheme.

The Talmadge Bill is similar to existing legislation (P.L. 92-603 Section 223) which sets limits on routine care reimbursement according to a classification scheme of hospitals. The major difference between the old and the new legislation is that the new Bill will seek to classify teaching hospitals as a new category. But any system of classification is likely to be troublesome, because classification cannot, by definition, accommodate unusual circumstances. For example, under the present scheme of classification, which is geographically based, Stanford stood to lose $4,000,000 simply by being grouped in Santa Clara County, rather than San Mateo County 500 yards to the north. After some negotiation, Stanford was granted exceptional status, and was reimbursed at a higher level, but such ad hoc procedures are hardly a satisfactory method of dealing with the law. Further, such a mode of classifying hospitals as a basis for reimbursement levels has led to a direct loss of reimbursement to Stanford of $500,000 over a 26 month period, if pending appeals are not successful.

In addition to these direct Federal proposals, State rate-setting regulations are also being debated in the Legislature in response to the Federal Government's increased incentives to the states to regulate their own hospital rates. All three sets of proposals are subject to intensive debate in the several legislative bodies, and thus the outcome is at present unclear.

What is more evident in the area of reimbursement regulations is both that reimbursement levels from Federal programs are below the actual cost of providing the care and that the gap between the public and private levels of reimbursement is growing. While this may be finally resolved toward some common level of reimbursement for both sectors, it is also clear that hospitals will stand or fall on those levels, which will offer no way of offsetting losses. At present, inadequate levels of public reimbursement are being met through increased private levels. With a common level of reimbursement for each group, levels must be adequate for the Hospital to survive financially. The alternatives will be to cut costs to the extent possible, and beyond that to reduce service levels. The whole process thus constitutes a balancing act which financial administrators must accomplish on a daily basis, seeking to equate low Federal funding with increased health care cost.

As the Federal Government moves into a position of increasing control of medical services, it seems likely that finance will be one of its major weapons, and that finance departments in hospitals will have little choice but to live within the financial limitations set by the Federal Government. In this context, the continual impact of regulations is readily understandable. Financial planning sets the conditions under which improvements, enlargements and changes of all kinds can take place. In some sense then, it is the front-runner in the debate between the Medical Center and the Government, and is therefore most strongly influenced by Federal workings. In its "umbrella" capacity as a servicer of all departments, it also bears the brunt of regulations affecting all those functions. Seen as unreasonably rigid in Government circles, and as unreasonably aggressive in the eyes of the doctors who are subject to it, the Department of Finance thus plays a central and difficult role. In common with other areas of the University, it is not only concerned with the functioning of an academic institution, but also a community service, and finally with a business, which must pay its way.

Perhaps the crucial dilemma in examining the impact of Federal regulations on financial matters is that of an increasingly strong government influence in a traditionally private environment. Government regulations, for example, prohibit reimbursement "to generate an excess of revenue over expense on Medi-Care and Medi-Cal patients." If such hospitals require the generation of an operating surplus to survive, they must do so in the face of governmental pressure not to pay for it. That leaves several alternatives. It may mean some accommodation between public and private sectors, an outcome which seems most likely in the

short-term. Or, as an alternative, health care levels may be reduced, a position which appears to be closer than is comfortable. Whatever eventuates, as Federal regulations continue to have their impact, it is likely that the Finance Department will be the first to know.

Facilities

In some ways the most complex set of interactions between government and any single unit of the Medical Center is found in the Facilities Department -- the unit responsible for the construction, renovation, and operation of the Physical Plant. The comlexity does not necessarily derive from the extent of the relationship or its cost -- though both are substantial -- but from the bewildering links among a mind-boggling group of standards-setting agencies -- federal, state, local, and non-governmental.

Though it provides a complex set of interactions between Government and Medical Center, Facilities also provides a rich supply of quantitative data to document the impact of Governmental regulations on building and maintenance. We can summarize the cost impact of Federal regulations on each section of Facilities as follows:

A. Facilities Department Budget ($5,000,000)

1. Public Safety: As an estimate, the equivalent of 50% of the Health Facilities Planning Budget is related to tracking, clarifying, implementing changes in regulations.
   Cost: $82,000 per year
2. Accountability: About 10% of the Engineering staff effort is spent meeting government requirements, for example, the Medicare requirement to identify costs by revenue center, a major impetus to a computerized work reporting system.
   Cost: $74,000 per year

B. Building Program Budget ($10,000,000)

About 4% of the Building Program budget is attributable to the increased costs of projects due to new and more rigorous government code compliance requirements of the past decade.
Cost: $400,000 per year

Again, as an estimate, perhaps 50% of the total of $556,000 would have been spent even without the increased presence of the government simply in response to ordinary desires to make facilities safer as the opportunities arise. Thus, in our estimate a total of $278,000 is being spent this year that is reasonably attributable to the incremental impact of government.

Costs deriving from Federal regulations are also evident in staffing. The Health Planning Group, for example, with a staff of four, deals primarily with the impact of Federal regulations, and seeks to ensure that Stanford complies with existing and forthcoming codes and regulations. Their particular job is further complicated by the fact that many Federal regulations imply additional requirements from state and private bodies to ensure full compliance. Five major examples of this Federal/state/private requirement system are listed below:

1. OSHA (federal law, state administration) standards implement the requirements of the American National Standards Institute (private).

2. Hill-Burton and Medi-Care (federal) require that National Fire Prevention Association (private) standards be implemented.

3. Medi-Care (federal) and Medi-Cal (state) "conditions of participation" require that NFPA (private) Life Safety Code and ANSI (private) standards be followed.

4. The Bureau of Health Insurance (federal) will automatically grant Medi-Care certification to hospitals which are fulfilling the standards of the Joint Commission on Accreditation of Hospitals (private), which in turn cross-reference the Life Safety Code of the NFDA (private).

The full extent of the interaction between Government and the Medical Center in the area of Facilities is provided by a list of the major codes affecting this area. 32 separate codes are most commonly cited, each with its own machinery for enforcement, inspection and reporting, to which the work of the Engineering Department is regularly subject.(Table 2)

In short, the Facilities Department provides some concrete evidence of the changes which Government has wrought on the Medical Center as an institution. The cost and staff consequences are clear and inevitable. Code compliance is not optional, it is mandatory. To assure compliance and to anticipate new requirements mean the expenditure of more money and more staff, and those have necessarily been forthcoming.

SUMC Engineering Standards

Engineering standards represent a functional and economical approach to maintenance, renovations and equipment installation throughout the SUMC Complex. Deviations from standards require justification based on significant functional or procedural benefits.

Part I: ENGINEERING STANDARDS

The Engineering Department, in performance of its functions, adheres to the latest codes and rulings per the following listings:

1. Hospital Licensing Act and Requirements
2. Regulations Relating to Health Faciliites Construction
3. California Administrative Code - S.B.519 Seismic
4. California Administrative Code - Public Health - Title 17
5. California Administrative Code - S.B.1930 Seismic
6. California Administrative Code - Public Safety - Title 19
7. California Administrative Code - Building Standards - Title 24
8. California Administrative Code - Licensing & Certification - Title 22
9. Uniform Building Code, Volume I, 1973 Edition
10. Uniform Building Code Standards for Volume I, 1973 Edition
11. Uniform Building Code, Volume II (Uniform Mechanical Code 1973 Edition)
12. Uniform Plumbing Code, 1967 Edition
13. Fire Prevention Code, 1965 Edition
14. Electrical Construction Materials List, August 1969 Edition
15. Fire Protection Equipment List, January 1969 Edition
16. Radiation Control for Fire and Other Emergency Forces
17. N.F.P.A. 13 Installation of Sprinkler Systems, 1971
18. N.F.P.A. 13A Care and Maintenance of Sprinkler Systems, 1973
19. N.F.P.A. 30 Flammable and Combustible Liquids Code, 1963
20. N.F.P.A. 56 Code for the Use of Flammable Anesthetics, 1965
21. N.F.P.A. 56A Standard for the Use of Inhalation Anesthetics, 1971
22. N.F.P.A. 56B Inhalation Therapy, 1968
23. N.F.P.A. 56C Hospital Laboratories, 1970
24. N.F.P.A. 56F Nonflammable Medical Gas Systems, 1970

Table 2

Table 2 (cont'd)

25. N.F.P.A. 70 National Electrical Code, 1974
26. N.F.P.A. 76A Essential Electrical Systems for Hospitals, 1971
27. N.F.P.A. 76BM Safe Use of Electricity in Hospitals
28. N.F.P.A. 76 CM High-Frequency Electrical Equipment in Hospitals, 1970
29. N.F.P.A. 90A Installation of Air Conditioning and Ventilating Systems,1969
30. Approved List Flame Retardent - Application Concerns Fabrics, Materials and Chemicals - September 1, 1970
31. Hospital Safety Manual - American Hospital Association
32. Joint Commission on Accreditation of Hospitals

The Office of Student Affairs

The Office of Student Affairs is concerned with the admission, support and progress of medical students at Stanford. The major changes which Federal regulations have brought about primarily concern admissions procedures, the handling of student records, and the control of student loan monies from the government. Six sets of regulations are of special importance:

1. The Family Educational Rights and Privacy Act, 1974 (The so-called Buckley Amendment).
2. Legislation relating to sex discrimination.
3. Regulations affecting financial aid to students.
4. The Health Manpower Act of 1971.
5. The Health Professions Educational Assistance Act of 1976.
6. Regulations relating to the handicapped.

Procedural Change

The impact of the regulations has taken many forms. The Buckley Amendment, for example, had most of its effect in fundamentally changing the procedures by which files about medical students are produced, made available and stored. While such procedural changes may appear slight, the effect on the institution has been considerable. To begin with, the initial period of adjustment to Buckley was difficult due to the imprecise nature of the law. The implementation of the new legislation occupied administrators for many months, until some commonality could be reached by various medical schools about appropriate responses.

While such changes are widely supported, both within the Medical School administration, and in a larger social setting, they nonetheless constitute major changes, which might well have been much more gradual had the Federal Government not intervened. In the area of student admissions, questions relating to sex of applicant are now expressly forbidden. Again, such a trend has widespread support, but the change would have been slower coming without Government intervention, and the consequences for the composition of the profession are not inconsiderable.

Admission Policy Change

Federal regulations act in other ways to change the composition of the student body, and thereby the long-term nature of the profession. It seems clear that

recent Government thinking about the adequacy of health care services has focused, in part, on the distribution of doctors, both geographically and by specialization. That the problem of a "lack of doctoring skills" is now seen as a distributional problem rather than simply a lack of doctors has led to some major legislative changes. The Health Manpower Act of 1971 addressed this problem of inadequate doctoring skills directly, and its action on the Medical School is through the Office of Student Affairs. To qualify for capitation funds, schools were required to enlarge their intake of medical students. In the case of Stanford, this led to an increase in the entering class from 74 to 86 in 1975-76. The impact on the training program was clearly considerable. An increase in numbers of this magnitude requires concomitant increases in training facilities, administrative services and teaching capacity. The changes will continue to be required during each subsequent year, as the enlarged cohort proceeds through the School. While these enrollment increases were widely supported within the institution, they have produced stresses on space, equipment, and clinical training opportunities, only some of which can be solved by the capitation money which was offered as the quid pro quo.

In contrast, the Health Professions Educational Assistance Act of 1976 seeks both to sustain the increased enrollments and in addition to change the distribution of doctors by specialty. Medical schools must comply with both conditions to continue to receive capitation funds.

The legislation seeks to redistribute doctors by specialty by making it a requirement that set percentages of residency slots be given over to areas of primary care. The Act requires that, in the first year of operation, 35% of such slots be so allocated, rising to 40% in the second year, and reaching a target of 50% in the third year. These are national targets, and should these targets be met nationally, Stanford will be little affected by the change. At present, 30% of Stanford's residency slots are allocated in the area of primary care. It appears that the national total is well over the required 35%, but should the national totals not be met in subsequent years, or should the law be changed to require institutional minimums, then there will be increasing pressure on Stanford and similar institutions to increase their quota in this area, a change which would not have been countenanced without outside pressure. This requirement appears to be a long-term problem for the Medical School.

Of more immediate concern is the requirement relating to the acceptance of transfer students from two-year colleges and from foreign medical schools. These transfer students are U.S. citizens who have completed Part One of the National Medical Board examination, and who are required to be admitted to the third year of training. Such transfers are to be admitted without regard to their academic record. Further, the number to be admitted is to be determined by the Secretary of HEW. This particular proposal, added almost as an afterthought to the legislation, has stirred a major controversy. Stanford and several other medical schools have said that this is so significant an erosion of their autonomy, that they will forego the benefits of the law rather than comply. The cost to Stanford would be $410,000 a year together with the exclusion of all of its students from the student loan program which the Act authorizes.

Financial Aid

A third major area of impact lies in the area of financial aid. While the procedural and admission policy changes described above have positive and negative consequences for the School, the impact on financial aids has been largely positive. The main policy implication for the School has been that Federal loan money has enabled Stanford to admit students from a wider socio-economic spectrum than would have been possible otherwise. It has therefore allowed Stanford to achieve a widely supported goal, and it is clear that without such a loan program the nature of the student body would be much altered. Prior to 1965, for example, virtually all student support was from personal sources. At present, Federal loans total half the available loan money, with Stanford providing an equal amount. Such changes in the nature of student support have clear implications for the nature of the student body and the resulting profession. For a University seeking to be responsive to community and national needs, this can only be seen as a major benefit of Federal intervention.

Conclusion

The impact of Federal regulations on student affairs is complicated and continuing. Recent developments in "handicapped" legislation make this point clear. While these new regulations will have a wide impact on many areas of activity in the Medical School and the Medical Center, the Office of Student Affairs is likely to

be concerned with their impact on admissions procedures. Present understandings seem to suggest that any questions relating to health, and not directly related to specific relevant abilities, will be out of order on applications for admission to the Medical School in the future. Obvious problems are generated by such procedures, which could lead, in extreme cases, for example, to the admission of students with a history of stress-related disorders to a training program and a profession which is by its very nature extremely stressful. It is still too early to say what the impact of such legislative changes will be on Medical School activities. Until the complications are sorted out, it will involve administrators in considerable effort, both in seeking to clarify how such changes are to be implemented, and also in trying to influence the legislature towards reasonable and informed legislation and the Department of Health, Education and Welfare toward reasonable regulations and enforcement procedures.

The most serious concern, however, remains that of protecting vital areas of institutional policy from government encroachment. As we have seen in one specific case, the consequences of resistance to one over-reaching act are direct financial costs amounting to some $410,000 for 1978-79. One must wonder whether Stanford can long afford, in any sense, to resist for long or over too wide a front. The costs of academic autonomy may be so large as to tax the resources of even the most well-endowed institutions.

It should not be said, however, that such difficult exchanges with Government are typical of the interchange between Government and the Office of Student Affairs. It is clear from our analysis that it is widely felt that Federal involvement in the area has had a largely positive influence. This is particularly true in the area of Financial Aids, but it is also true in other ways. One clear example is provided by the experience with the Buckley Amendment. Officials of the Office of Student Affairs believe that the legislation has led to a more rigorous scrutiny of material that enters a student's file, a lessening of student anxiety about file material, and an atmosphere of openness which might not otherwise have been present. If we begin to see Federal involvement as largely an unwanted presence in the workings of Medical School and Center, the experience of the Office of Student Affairs provides a useful example to the contrary.

Research

The management of research in an institution that is home to as much research as is the Stanford University Medical Center is bound to be a large and costly enterprise. Similarly, when one patron supplies as large a share of the funds for research as the federal government does for biomedical research, then conflict, tension, and mutual irritation are bound to be present in the relationship.

Both of those statements are true for the Stanford Medical Center, but they are equally true for the School of Engineering, the Department of Physics, and other parts of the University that are heavily involved in research. We have chosen therefore, not to focus on the bread and butter of research administration. We recognize that our choice obscures from our view one of the largest continuing areas of interaction between the Medical Center and the Government. We hope, however, that what we ignore will be seen by others who are studying research-oriented universities. What we have looked at, instead, are several aspects of research administration whose effects are felt, if not uniquely then at least disproportionately in biomedical research. We have examined the areas of research involving human subjects and research involving animals. In addition, we have some preliminary observations about the new regulation of Recombinant DNA research.

Human Subjects Review

In one respect there is a body of research carried on in the Medical Center that is unique to the University: Clinical research on human subjects intervenes directly into people's lives, frequently at a time when they are sick and vulnerable, and its effect can be significantly beneficial or detrimental to the health and well-being of the objects of the research. The justification for permitting research of that description is that its benefits -- perhaps to the individual subject, but more likely to others, will outweigh the risks.

However, one can concede those benefits fully and still insist on careful monitoring of the conduct of such research for a variety of reasons that do not challenge the implicit risk-benefit analysis that permits experimentation on human beings. This the government has done, and in response to political pressures and perhaps a growing sensitivity to ethical questions in society, an elaborate body of rules has been developed in the last decade to protect the rights and safety of human subjects in research.

The impact on the Medical Center has been enormous. We were given a careful, though approximate, assessment of the cost of doing business under these regulations. The Human Subjects Review Committee, which consists of faculty, administrators, outside physicians, and lay persons consumes an estimated 3000 man hours per year (exclusive of the time of Principal Investigators in filling out the required forms). The Committee processes more than 600 applications per year and requires one full-time administrator, sixteen file drawers and 200 square feet of space. A fair estimate of the total cost (not all of which is out-of-pocket) was given as $70,000 per year.

While those are the easiest costs to identify, they may be the least important. We were given strong assertions, though without documentation, that the difficulties of using human subjects are becoming so great that scientists are turning instead to animal subjects or away from live body research altogether. This seems to us an extremely important subject to inquire into in more detail. If there is a flight from research on humans as our indications and some recent writing suggest,[1] then any rational view of the value of regulation would need somehow to account for that loss. We urge the Sloan Commission to look into this matter.

Animal Care

If scientists are turning to animals because of the restrictions on research involving humans, they may be in for a surprise. The use of animals, too, has become more costly and subject to more detailed regulation. Here, the estimate given us is that the Administrative Panel on Laboratory Animal Care costs $5000 annually, and that the cost of complying with NIH regulations has risen to about $20,000 a year.

Those who work with these regulations do not argue that they are unreasonable on their face. Their concern is that the increasing costs of animal care mandated by tighter rules come at a time when research funds are not growing, and the inevitable result is more care and less research. Depending on society's dominant values, that may well be seen as a fair trade, but it is foolish to assume that it is without a careful examination of the social costs of research delayed or foregone.

[1] A sober -- and sobering -- discussion of this issue may be found in Jean D. Lockhart, "Pediatric Drug Testing: Is it at Risk?", Hastings Center Report, June, 1977.

Recombinant DNA Research

This is not the place to attempt an examination of the very difficult questions that have been raised in the debate over whether and how to regulate the safety of this new research tool. It is sufficient for present purposes to point out that we may well be approaching a new definition of the government's relationship to the conduct of biomedical research. Starting with a warning, raised by scientists themselves, about the possible dangers of certain specific types of experiments, the debate has moved into the Congress and toward the most detailed and potentially intrusive regulation of university laboratories in history.

Beyond that, it is the explicit intention of the leading advocate of regulation in the Senate, Senator Edward Kennedy, to use the regulation of this body of research to establish in principle and in practice the right of the lay public to a major (in fact majority) voice in what research shall be done and how it shall be conducted.

In our view this is not a difference merely of degree from existing policy, but a difference of kind from the approach that has prevailed with even the most hazardous kinds of research. It is a development to be watched with great care.

Legal Services

If one were limited to a single measure of the growth of the regulatory presence in modern organization, the increase in the number of lawyers employed would serve as well as any. Lawyers are to regulation what the clergy are to religion; in their daily work each provides the authoritative interpretations of the rules by which their clients/communicants must live.

Prior to 1973, the Stanford University Medical Center borrowed from elsewhere in the University Administration half the time of one attorney. Today, the Office of Legal Counsel consists of four FTE attorneys. In addition, malpractice litigation is handled by lawyers for the insurance carrier and virtually all other litigation is handled by outside counsel, frequently in consultation with internal counsel. The staff counsel practice what might best be called "preventive law." Their responsibilities fall into four main areas -- academic, patient care, general business law, and government regulations. The last of those accounts for about half their total effort. If we examine the workload of one staff lawyer, the Associate Counsel for Medical Affairs, we can gain some insight into the way in which legal effort is spent in response to Federal regulations.

The Associate Counsel for Medical Affairs estimates that about 75% of his time is spent on evaluating, negotiating, interpreting and insuring compliance with Federal laws and regulations. Table 3 was prepared by him to give some flavor of the number and variety of matters encompassed under those headings.

Quite clearly, the list changes from time to time, and the distribution of effort within it will change over time. For example, the Employee Retirement Income Security Act has been a major preoccupation of the Associate Counsel. As the administration of the Act becomes better understood and more routine, it will be less demanding of legal attention, except at those times at which it is amended. The Internal Revenue Code work having to do with tax exemption stems directly from the recent establishment within IRS of an office to examine the returns of non-profit institutions for the purpose, among others, of identifying unrelated business income. Thus, the Associate Counsel has in the past reviewed the Medical Center's return before it was submitted, and then dealt with the IRS audit. While this is not an annual exercise for the Associate Counsel, issues arising from the process each year may need to be dealt with by him.

Medi-Careand Medicaid constitute the largest single focus of the Associate Counsel's time. He reviews cost reports with government auditors and he prepares and presses administrative appeals from denials of reimbursements. The entire process from cost report to disposition of appeal will typically take 1-1/2 years, so several are in motion at any one time. It is predictable that, as government financing of medical care grows, so will the number of lawyers required to deal with its complexities.

The Medical School lawyer thus acts as the interpreter, advisor and prophet with regard to Federal regulation. Advice is sought by many of the Center's departments on matters of interpretation, which may have major impact on various functions. The lawyer's office also seeks to keep the Center informed on likely changes in the law which will affect Center operations in the future.

Lawyers play a unique role in the life of the Medical Center. As a new specialization, medical law is a growing concern, and it is so primarily because of the growth of Federal activity in the area.

It is a reasonable hypothesis to suggest that the work of lawyers, more than any other group, changes the life of the institution. In the case of Stanford, they provide the link between Government rule and institutional behavior. While they do not cause social and institutional change, they are often the agents of change. And the increased and increasing need for their agency reveals much about our present condition.

ESTIMATE OF PERCENT OF MY TIME DEVOTED TO COMPLYING WITH THE FOLLOWING FEDERAL AUTHORITIES

AUTHORITIES	PERCENT OF TOTAL TIME
1. Public Health Service Act of 1971	1%
2. Social Security Act	1%
3. Employee Retirement Income Security Act (ERISA)1974	15%
4. IRS Code - Tax Exemption	5%
5. IRS Code - Deductible Contributions	1%
6. IRS Code - Nondiscrimination Provisions	1%
7. Tax Reform Act of 1976	1%
8. Immigration and Naturalization Act of 1891	1%
9. Health Professional Educational Assistance Act of 1976	5%
10. Pension Liability Insurance	3%
11. Medi-Care and Medicaid	20%
12. Hospital Survey and Construction Act (Hill-Burton)	10%
13. Professional Standards Review Organization	5%
14. National Health Planning and Development Act of 1974	6%
	75%
Other Legal Matters not involving Compliance with Federal Authorities	25%
TOTAL	100%

Table 3

Conclusions and a Look into the Future

There are few forces in any modern society as powerful and pervasive as an active government. One observation beyond argument is that in the last 15 years the American government has been active in a number of areas that engage the interests of colleges and universities. As a result, institutions of higher education have changed in important ways. A broad generalization will perhaps suffice to cover a larger number of corollary truths: administrative functions in universities have become larger, more numerous, more costly, and more intrusive into the life of the institutions. To a very substantial extent, those functions have grown in order to do business with the government of the United States.

Our brief, and necessarily incomplete, study of the Stanford University Medical Center gives substance to that generalization. While a part of a larger university, the Medical Center is both a kind of university in its own right and it is something else that universities typically are not, namely the purveyor of a consumer service of enormous public importance. That combination makes it the object of most of the social forces that affect the main institution, as well as a different set that is unique to the Medical Center's role as supplier of health care to the public. As we look to the future later in this section, we shall ponder whether the ways in which the government acts on the Medical Center are likely to remain unique, or whether they may spread to affect relations with the rest of the university.

What, then, does it all add up to? We have seen a number of tangible, specific institutional responses to governmental activity. In every department we studied, we found increases in personnel and other costs in order to anticipate, interpret and comply with government rules. Some entire sections -- for example, the Health Planning Group -- exist for no other reason. And it is not too much to say that the need to deal with the government effectively has produced a new subspecialty -- the medical lawyer.

But we have a sense that what is happening goes beyond the data we were able to gather. For example, we were met, eveywhere we went, with extraordinary cooperation, even though we were asking people to do extra work on a short time schedule. More than that, however, we were struck by the eagerness of people to talk about

the impact of government on their working lives. It was as if they had been storing up a load of thought and feeling and had been waiting for someone to ask the right question. We found their reaction impressive and revealing.

What we heard would not have given comfort either to a deep-dyed conservative or to a committed liberal. Almost without exception, those to whom we talked spoke of the benefits of the government programs with which they worked. That is perhaps not surprising in an area like Student Services, where the benefits of government activity are visible every day in the lives of students. It is more surprising in those areas where the interaction is primarily regulatory in nature. However, even in those parts of the institution there was a broad recognition of the desirability of the purposes of regulation and the benefits of many of the altered practices which have resulted from it. Better personnel policies, more careful treatment of human subjects in research, improved animal care, tighter financial controls, improved building and operating safety -- all of these are seen as healthy results of governmental initiatives.

It is important to keep that in mind in assessing the net effect of the government's presence, for as our respondents tell us, and as we saw for ourselves, it is not easy to strike a balance of pluses and minuses. If many of the results are in themselves desirable, the pace at which they come, the costs that accompany them, and the sheer difficulty of managing them are often far less so. The problems range from trivial to fundamental. A small example neatly captures the range.

The Civil Rights Act of 1964 surely deserves that much overworked term "landmark." Its passage was a high point in the long struggle toward equal opportunity for all Americans. As it happens, one of the regulations issued pursuant to Title VII of the Act required institutions to retain all applications for employment for a period of six months, so that evidence of grievances would be available for a reasonable time.

In 1967 the Congress enacted the Age Discrimination Act of 1967. Regulations issued in pursuance of that Act required that all employment applications be retained for a period of one year. Given some 10,000 applications annually at the Medical Center, that single change ultimately required the hiring of one additional full-time person to handle the added work of filing and purging files, and an expenditure of close to $1000 for additional files.

It is a small, almost trivial, example, but the questions it raises are neither. Did anyone in the Executive Branch know of the differing requirements? Did anyone consider the cost of extending the period of retention? Did anyone have reason to believe that one year is better than six months, and was there any evidence adduced that the shorter period was inadequate? There is good reason to believe that the answer to all those questions is no, for only a half dozen years later, the Internal Revenue Service proposed its own non-discrimination regulations which included a mandatory three year retention period for all records. There was no indication then that the IRS was even aware of the existing rules of other agencies which governed exactly the same matter.

In part, such problems arise from the sheer size and clumsiness of the federal establishment. In further part, however, they are the product of the process by which such rules are devised. That process consists of organized and articulate groups pressing for the redress of a perceived injustice. Their force, both political and moral, frequently overwhelms such complications as questions of timing, the capacity of institutions to respond and the relationship among problems and among the remedies for problems. All such questions tend to be seen merely as excuses for delay. But if justice delayed is justice not done, it is also true that both the cause of justice and of the institutions that must be the instruments of justice can be undone by thoughtless haste. Somehow, the processes of policy making must balance both of those truths better than they have done so far.

As always, the past seems simple, the present complicated and the future muddy. However, some predictions about the future can be made with unusual confidence. The most important is that the present influence of the Federal Government on the Medical Center is just a forshadowing of much deeper and more pervasive controls to come. The reason is that medical training, research, and care are important, expensive, and dependent on government financing -- and in all of those respects becoming more so.

In the area of patient care, it is as clear as anything can be that the nation is moving toward some form of universal health insurance. Control of hospital and medical costs is an inevitable corollary of that development, and tighter controls on service levels must accompany cost control. None of that is speculation. Some degree of cost and service control already exists, and more is now actively being sought by the Administration and the Congress.

Similarly, assessments of physician supply and distribution have and will affect the form and content of medical training. In response to a perceived shortage of physicians a decade ago, medical schools have doubled their capacity. We now have what is increasingly seen as a doctor surplus. How this perception will be translated into policy is not yet clear, but that it will be translated into policy can be doubted only by the innocent. What is alleged to be an excess of specialists and a shortage of family physicians has already produced a mandated minimum proportion of primary care residencies as a condition for receiving Federal capitation funds. And the current controversy over the required admission of American medical students in foreign medical schools without regard to their academic quality casts serious doubt on the capacity of the Congress to refrain from using its enormous leverage in medical schools to solve peripheral, special interest problems.

The growing inclination of the government to intervene in the conduct of biomedical research is yet another indication of the shape of the future. The apparatus now in place for the regulation of research involving human subjects stands as a model for one of the leading proposals for the regulation of Recombinant DNA research, and both suggest that all biomedical research will be subject to more intensive scrutiny and regulation in the near future.

It should be noted that those are related, not isolated trends. The high cost of medical care and the forthcoming national health insurance programs are directly connected to the belief that there are now too many expensive specialists and not enough lower cost generalist physicians. Similarly, the increased attention to biomedical research is given force by the argument that too much of that research is unrelated to the cure of disease or is (paradoxically) directed to the development of expensive technology used by high cost specialists who attend to only a small fraction of the nation's real health problems.

It is a complicated, devilishly difficult set of issues, and university medical centers are the places where many of them intersect. We call special attention to the word "university," for it seems to us unlikely that developments of such import in one part of an institution can occur without effect to the rest of the institution. We note, for example, that the same Congress that legislates and appropriates for medical education and research also passes laws and votes money for other programs of education and research. If it is acceptable practice to override institutional admissions standards in the medical school, then given

the perception of a good enough reason, it is equally acceptable elsewhere. If local and national committees-of-review to assess the consequences of research involving human subjects and Recombinant DNA are sound public policy, then only the discovery of real or imagined risk is required to generate similar apparatus for other kinds of research.

We do not think that we are conjuring up nightmare visions or parading fears about a remote future. In the world of the medical center the future that concerns us is here and more is coming. It would be imprudent to think that its spread can be prevented by quarantine or by ignoring the existence of the disease. The university must attend to what is happening to one of its parts. We see that as the main message of our study.

Questionnaire/The Impact of Federal Regulations on the Medical School and the Medical Center

I. During the last 10 years, have you and/or your office had to change or restructure additional procedures to comply with Federal regulations? If so, please identify:
   (A) The nature of the regulation(s).
   (B) The nature of the changes.

II. If the answer to question I is yes, please provide estimates man-hours and/or costs involved.

III. If the answer to question I is yes, did you or your office:
   (A) Engage additional personnel to perform any administrative functions?
   (B) Maintain additional records for the sake of any new duties?
   (C) Acquire additional space for the performance of any new duties?
   (D) Purchase and/or lease equipment for the performance of new duties?
   (E) Utilize additional computer time because of these additional duties?

IV. Regardless of whether the regulations are recent or old, identify any recurring activity on your part or that of your staff, required to comply with effecting Federal regulations, and not described above.

V. Regardless of whether the regulations are recent or old, identify the different kinds of reports that you or your office must submit to comply with the Federal regulation or regulations. Please attach sampled copies of each kind of report.

VI. Do you serve on any committee or subcommittee within the university where a significant share of its activities are mandated by Federal regulations? If so, which ones?

VII. Some regulations restrict rather than mandate activities. Are you aware of any Federal regulations that have necessitated restrictions to the performance of your professional and/or administrative duties within the last 5 years? If so, please specify.

VIII. Do you have any specific example of communication differences or other administrative problems generated by efforts to comply with Federal regulations? Please site.

IX. Can you identify any benefits that have accrued to your operation of the Medical School/Center, as a result of Federal regulations?